Docket No.: 600-1-081CONCIP
(PATENT)

AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ralph Steinman *et al.*

Application No.: 09/925,284 Art Unit: 1644

Filed: August 9, 2001 Examiner: Ronald B. Schwadron

For: ENHANCED ANTIGEN DELIVERY AND MODULATION OF THE IMMUNE RESPONSE THEREFROM

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

As indicated in the Notice of Appeal filed on June 28, 2006, Appellants hereby appeal the final decision of the Examiner in the above-identified application rejecting the subject matter of the pending claims. For the reasons set forth in this brief, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the Examiner's final rejection of the claimed subject matter. A petition for a three month extension of time as a large entity and a check for $1, 020.00 is enclosed herewith.

I. REAL PARTY IN INTEREST

The real party in interest in the above-identified application is Rockefeller University, the assignee of the application.

II. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal and related Pre-Appeal Brief Request for Review were filed on June 28, 2006 in the parent application, U.S.S.N.: 09/586,704, having a filing date of June 5, 2000. No related interferences are known to Appellants, which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-21 are pending in this application. Claims 1-5 and 10-12 have been withdrawn from consideration.

Claims 6-9 and 13-21 are on appeal and are set forth in the Claims Appendix (Appendix A).

IV. STATUS OF THE AMENDMENTS

A Notice of Appeal was filed June 28, 2006. All prior amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 6-9

The claims on appeal are drawn to methods for enhancing tolerance to a preselected antigen in a mammal, comprising exposing *ex vivo* or *in vivo* dendritic cells from the mammal to a vaccine conjugate that comprises the preselected antigen covalently bound to an anti-human DEC-205 antibody, or an anti-murine DEC-205 antibody that binds to human DEC-205, under conditions that promote dendritic cell quiescence, wherein the human DEC-205 protein comprises the amino acid sequence of SEQ ID NO: 7. The amino acid sequence of SEQ ID NO:7 corresponds to a partial (C-terminal) sequence of human DEC-205 (see, for example, page 11, lines 1-16; page 18,

lines 5-10; page 25, line 16 through page 26, line 5; page 27, lines 13-17 of the specification as originally filed).

Claims 13-17

The claims on appeal are further drawn to methods for enhancing tolerance to a preselected antigen for which tolerance is desired in a mammal, comprising exposing *ex vivo* or *in vivo* dendritic cells from said mammal to a conjugate comprising said preselected antigen covalently bound to an anti-human DEC-205 antibody (claim 13) or anti-murine DEC-205 antibody (claim 14), wherein the antibody is reactive with an amino acid sequence as set forth in SEQ ID NO: 7. As noted above, the amino acid sequence of SEQ ID NO:7 corresponds to a partial (C-terminal) sequence of human DEC-205 (see, for example, page 11, lines 1-16; page 18, lines 5-10; page 25, line 16 through page 26, line 5; page 27, lines 13-17 of the specification as originally filed).

Claims 18-21

The claims on appeal are also drawn to methods for enhancing tolerance to a preselected antigen in a mammal comprising exposing *ex vivo* or *in vivo* dendritic cells from the mammal to a conjugate comprising the preselected antigen bound to an anti-mouse DEC-205 antibody that cross-reacts with human DEC-205, under conditions that promote dendritic cell quiescence, wherein the mouse DEC-205 protein comprises the amino acid sequence of SEQ ID NO: 10. The amino acid sequence of SEQ ID NO:10 corresponds to the full-length sequence of mouse DEC-205 (see, for example, page 11, lines 1-16; page 18, lines 5-10; page 25, line 16 through page 26, line 5; page 27, lines 13-17 of the specification as originally filed).

Also, see the full length mouse DEC-205 sequence (SEQ ID NO: 3) in the parent application, U.S.S.N. 09/586,704, which was incorporated by reference in its entirety in the present application, U.S.S.N. 09/925,284. Please also see the Substitute Sequence Listing submitted in the present application on December 22, 2005, which identifies the full length mouse DEC-205 sequence as SEQ ID NO: 10.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants present the following issue for review:

1. Whether claims 6-9 and 13-21 are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

2. Whether claims 6-9 and 13-17 are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

VII. ARGUMENTS

A. Summary of Examiner's Rejection of Claims 6-9 and 13-21 Under 35 U.S.C. § 112, First Paragraph, as Failing to Comply with the Written Description Requirement

The Examiner has rejected claims 6-9 and 13-21 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the specification does not provide adequate written description for the claimed invention because, while the specification discloses the full length sequence of murine DEC-205 protein, it only discloses a partial sequence for human DEC-205. The Examiner asserts that, because human DEC-205 is approximately 1800 amino acids in length, the recitation in the claim of a 30 or 25 amino acid sequence derived from human DEC-205 does not provide adequate written description of a molecule that is almost 1800 amino acids in length. The Examiner further asserts that the claims encompass antibodies that bind any immunogenic epitope on the approximately 1775 undisclosed amino acids of DEC 205, and that the term human DEC-205 presumably encompasses full length human DEC-205, as well as undescribed mutants and alleles of human DEC-205.

B. Appellants' Response

1. Each Independent Claim Requires Separate Consideration

Appellants respectfully disagree with the Examiner's rejection. As a preliminary matter, the scope of claims 6-9 and 13-21 varies and, as such, the assertions made by the Examiner are not equally applicable to all of these claims.

Specifically, contrary to the Examiner's opinion that the claimed antibody conjugates do not bind to any specific epitope of human DEC-205, claims 13-17 are drawn to antibody conjugates which do, indeed, bind to a particular epitope of human DEC-205, namely the C-terminal sequence (SEQ ID NO: 7).

Similarly, that the present specification teaches a partial human DEC-205 sequence is also irrelevant with respect to claims 18-21, since these claims are drawn to methods employing antibody conjugates that bind to *full length murine DEC-205*

protein (SEQ ID NO: 10). Thus, the Examiner's statement that the antibody conjugates of claims 18-21 bind to "undisclosed amino acids of DEC 205" is incorrect. Indeed, the full length sequence of murine DEC 205 is explicitly provided in the present application as SEQ ID NO: 10. Moreover, while the antibody conjugates of claims 18-21 also cross-react with human DEC-205, the epitopes of human DEC-205 that the conjugates bind to are thus, by definition, shared with (i.e., cross-reactive with) murine DEC-205. As such, the sequence of these epitopes is provided as part of the full length murine DEC-205 sequence recited in the claims (SEQ ID NO:10).

For at least the reasons above, the reasons provided by the Examiner for rejecting claims 13-17 and 18-21 as lacking written description under 35 U.S.C. §112, first paragraph, do not apply or support the rejection.

Finally, with respect to claims 6- 9, drawn to methods which employ antibody conjugates that bind to human DEC-205 protein comprising the partial amino acid sequence of SEQ ID NO:7, Appellants respectfully submit that while Appellants' specification does not recite the full length human DEC-205 sequence, or the sequence of each and every variant of human DEC-205, this does not *de facto* mean that the pending claims fail to comply with the written description requirement. Importantly, it is well-established that the written description standard is not a bright line test, but instead takes into consideration a number of different factors. As discussed in detail below, Appellants' disclosure of the partial human DEC-205 sequence and the full length murine DEC-205 sequence, in combination with knowledge available in the art, were sufficient to demonstrate to one of ordinary skill that they had full possession of the complete human DEC-205 protein, and antibody conjugates against the protein, at the time the present application was filed.

2. The Descriptive Text Needed to Satisfy the Written Description Standard Must be Considered in Relation to the Scientific Knowledge in Existence at the time of the Invention, the Skill in the Art, and Correlation of a Disclosed Function to a Known Structure

The mere fact that Appellants' specification does not recite the full length human DEC-205 sequence does not alone mean that any of the claims on appeal fail to comply with the written description requirement.

Moreover, Appellants respectfully disagree with the Examiner's assertion that the decision in *Capon v. Eshhar* (418 F.3d 1349, 1357 (Fed. Cir. 2005)) "is not relevant to the claims under consideration." While the claims on appeal may differ from the claims on appeal in *Capon v. Eshhar*, the Court took considerable effort to lay out the underlying framework for determining written description in other cases moving forward, and to clarify that written description, like enablement, must be determined on a case by case basis. Specifically, the standard for meeting the written description requirement and showing possession of the claimed invention, as articulated by *Capon v. Eshhar*, differs for every patent specification depending upon a number of factors, including the scientific knowledge in existence at the time of the invention, the skill in the art, the predictability of the claimed subject matter, and correlation of a described function to a known structure. Again, Appellants do not argue that the claims at issue in *Capon v. Eshhar* were the same as in the present case, rather that the written description standard articulated by the Court, when applied in the present case, is fully satisfied.

Specifically, as discussed further below, the maturity of the science and skill in the art at the filing date of the present invention were such that one of ordinary skill could predictably obtain full-length proteins, such as DEC-205, based on partial sequences, as well as predictably obtain antibodies against the full-length protein (or any region or variants of the protein). As such, Appellants teachings in the specification, combined with the knowledge available in the art, demonstrate that Appellants were in full possession of the presently claimed invention at the time of filing.

3. Isolation and Cloning of Proteins, and Generation of Antibodies Were Highly Mature Technologies at the Time of the Present Invention

Indeed, at the filing date of the present application (*i.e.*, in 1995), technologies for isolating, characterizing and cloning proteins were highly developed, as were technologies for generating antibodies against such proteins. For example, several well known techniques were available for cloning proteins, including human DEC-205, based on a given partial amino acid sequence of the protein (see, for example, page 20, line 30 through page 21, lines 1-19; as well as page 25, lines 25-31 through page 31, lines 1-16 of the parent application, USSN 09/586,704). Additionally, techniques for

expressing cloned proteins (see, for example, page 31, lines 18-31 through page 35, lines 1-30 of the parent application, USSN 09/586,704) and for generating antibodies against the proteins were equally well known (see, for example, page 42, lines 23-31 through page 45, lines 1-19, and particularly page 42, lines 28-31 in the parent application, USSN 09/586,704). Once armed with a partial amino acid (*i.e.,* a peptide derived from a given protein), it was also well within the skill of the art to use these techniques to generate antibodies against such peptides and to isolate the full-length protein from its natural source.

Appellants specifically illustrated this in relation to mouse DEC-205. In particular, Appellants successfully isolated and characterize full-length mouse DEC-205 from whole murine thymus using mAb NLDC-145, an anti-mouse DEC-205 antibody (see page 63 of the parent application, USSN 09/586,704). Additionally, Appellants successfully raised antibodies against N-terminal peptides from mouse DEC-205 protein (see, for example, page 62, lines 26-32 and page 63, lines 1-15 of the parent application, USSN 09/586,704). This provides ***clear evidence*** that the partial human DEC-205 sequence described in the present disclosure put Appellants in possession of the complete DEC-205 protein and antibodies against the protein.

Additionally, in the present application, Appellants teach a partial (C-terminal) sequence (SEQ ID NO.:7) of human DEC-205 protein. Appellants further teach the highly homologous full-length sequence of mouse DEC-205 protein (SEQ ID NO.:10), along with an in-depth characterization of this protein (including its ability to deliver antigen to an active antigen processing compartment of dendritic cells). Appellants also describe well-known techniques for cloning proteins (including human DEC-205) based on a given partial amino acid sequence of the protein, expressing cloned proteins and generating antibodies against the proteins. Based on these teachings, it was well within the skill of the art to have generated anti-DEC-205 antibodies. It was also well within the skill in the art to have generated full-length human DEC-205 protein, as well as variants of the human DEC-205 protein.

In fact, as evidenced by the Declaration by Dr. Michel Nussensweig (Appendix B), the cloning techniques and techniques for generating antibodies described in the specification were ultimately successfully used to clone and isolate human DEC-205 and to produce antibodies against full-length human DEC-205. This provides clear evidence that Appellants were in fact indeed in possession of the claimed invention

based on the descriptive text provided within the four corners of Appellants' originally filed disclosure.

4. The Structure and Function of Human DEC-205 Correlates to the Structure and Function of Mouse DEC-205 Protein

Finally, the Written Description requirement may be satisfied if the disclosed function of the claimed invention sufficiently correlates to a particular, known structure. In the present case, the structure and function of human DEC-205 clearly correlates to that of mouse DEC-205, the characteristics of which (including full-length sequence) are described in detail in the present disclosure. Accordingly, the fact that Appellants provide an in-depth characterization of mouse DEC-205, including its full-length sequence, which correlates to human DEC-205, provides further basis for fully meeting the Written Description requirement.

In sum, the teachings set forth in Appellants' specification, in combination with the high level of skill and knowledge in the art at the time of the invention, and the proven predictability of the technologies involved in the invention, clearly satisfies the standard for Written Description according to the guidelines articulated by the CAFC in *Capon v. Eshhar* (CAFC 2005), and demonstrates possession of the claimed invention.

C. Summary of Examiner's Rejection of Claims 6-9 and 13-17 Under 35 U.S.C. § 112, First Paragraph, as Failing to Comply with the Written Description Requirement

The Examiner has rejected claims 6-9 and 13-17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that there is no support in the specification for a human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID NO.:7. The Examiner further asserts that, although the specification teaches that SEQ ID NO.:7 is a peptide derived from DEC-205, there is no support for a DEC-205 protein comprising the peptide wherein the molecule could have any amino acids in association with the aforementioned sequences recited in the claim.

D. Appellants' Response

As an initial point, it is unclear to Appellants, based on the Examiner's comments, what the distinction is between the former 35 U.S.C. § 112, first paragraph, rejection of claims 6-9 and 13-21, and the present § 112, first paragraph, rejection of claims 6-9 and 13-17. Indeed, both rejections appear to be based on the same premise, *i.e*, that the claims lack written description because the specification teaches a partial human DEC 205 sequence. Appellants note, however, that the former rejection has been applied to claims 6-9 and 13-21, whereas the present rejection has been applied only to claims 6-9 and 13-17.

Accordingly, with respect to claims 13-17, Appellants again respectfully note that these claims are drawn to methods that employ antibody conjugates defined as binding to a *particular* epitope on human DEC 205, the sequence of which is explicitly taught in the application (SEQ ID NO:7). Therefore, the Examiner's assertion that the specification fails to provide support for a human DEC 205 protein comprising the partial sequence of SEQ ID NO:7 does not provide a basis for rejecting claims 13-17 for lack of written description.

Moreover, for the many reasons discussed above in Section B, Appellants respectfully submit that the specification does indeed provide full support for a human DEC 205 protein comprising SEQ ID NO:7, as recited in claims 6-9. Again, the mere fact that the disclosure teaches partial sequences for human DEC 205 does not alone mean that the claims covering antibody conjugates which bind to human DEC 205 comprising such sequences lack written description. Whether claims 6-9 comply with § 112, first paragraph, depends on a variety of factors, as discussed above in relation to the previous rejection (Section B). When applied in the present case, given the teachings in Appellants' specification, in combination with the skill and knowledge available in the art at the time the present application was filed, clearly demonstrate that Appellants possessed the complete human DEC-205 protein recited in claims 6-9.

As previously discussed in detail, Appellants teach the partial C-terminal sequence of human DEC-205 (SEQ ID NO: 7). Based on this partial amino acid sequence, it was well within the skill of the art to have used known techniques to generate antibodies against this peptide, and to have predictably isolated the full-length protein or variants from its natural source. In fact, the maturity of the science and skill in the art at the time of the present invention were such that those of ordinary skill in the art were routinely obtaining full-length proteins based on partial sequences, as well

as predictably obtaining antibodies against such full-length proteins . This is specifically attested to in the Declaration submitted by Declaration by Dr. Michel Nussensweig (Appendix B). Further, the fact that Appellants provide an in-depth characterization of mouse DEC-205, including its full-length sequence, which correlates to human DEC-205, provides further basis for fully meeting the Written Description requirement.

In sum, for at least the foregoing reasons, claims 6-9 and 13-21 fully comply with 35 U.S.C. § 112, first paragraph.

VIII. CONCLUSION

Appellants submit that claims 6-9 and 13-21 comply with the written description requirement under 35 U.S.C. § 112, first paragraph, and respectfully request that the Board reverse the rejection of claims 6- 9 and 13-21 for the reasons set forth above.

Dated: May 14, 2007

Respectfully submitted,

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CLAIMS APPENDIX A

6. (Previously Presented) A method for enhancing the development of tolerance to a preselected antigen for which tolerance is desired, in a mammal comprising exposing ex vivo or in vivo dendritic cells from said mammal to a conjugate comprising said preselected antigen covalently bound to an anti-human DEC-205 antibody or an anti-murine DEC-205 antibody that binds to human DEC-205 under conditions that promote dendritic cell quiescence, said human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID NO: 7, and wherein said preselected antigen is selected from the group consisting of allergens, autoantigens and antigens participating in allograft rejection.

7. (Original) The method of claim 6 wherein said preselected antigen is a peptide antigen or a protein antigen.

8. (Original) The method of claim 7 wherein said peptide or protein is conjugated to said antibody to DEC-205 by means of a cross-linking agent.

9. (Original) The method of claim 7 wherein a light chain or a heavy chain of said antibody to DEC-205, and said peptide antigen or protein antigen, are present on a single polypeptide chain.

13. (Previously Presented) A method for enhancing the development of tolerance to a preselected antigen for which tolerance is desired in a mammal, comprising exposing ex vivo or in vivo dendritic cells from said mammal to a conjugate comprising said preselected antigen covalently bound to an anti-human DEC-205 antibody, wherein the antibody is reactive with an amino acid sequence as set forth in SEQ ID NO: 7, under conditions that promote dendritic cell quiescence, wherein said preselected antigen is selected from the group consisting of allergens, autoantigens and antigens participating in allograft rejection.

14. (Previously Presented) A method for enhancing the development of tolerance to a preselected antigen for which tolerance is desired, in a mammal comprising exposing ex vivo or in vivo dendritic cells from said mammal to a conjugate comprising said

preselected antigen covalently bound to an anti-murine DEC-205 antibody, wherein the antibody is reactive with an amino acid sequence as set forth in SEQ ID NO: 7, under conditions that promote dendritic cell quiescence, and wherein said preselected antigen is selected from the group consisting of allergens, autoantigens and antigens participating in allograft rejection.

15. (Previously Presented) The method of either one of claims 13 or 14, wherein said preselected antigen is a peptide antigen or a protein antigen.

16. (Previously Presented) The method of either one of claims 13 or 14, wherein said peptide or protein antigen is conjugated to said antibody to DEC-205 by means of a cross-linking agent.

17. (Previously Presented) The method of either one of claims 13 or 14, wherein a light chain or a heavy chain of said antibody to DEC-205, and said peptide antigen or protein antigen, are present on a single polypeptide chain.

18. (Previously Presented) A method for enhancing the development of tolerance to a preselected antigen in a mammal, the method comprising exposing ex vivo or in vivo dendritic cells from the mammal to a conjugate comprising the preselected antigen bound to an anti-mouse DEC-205 antibody that cross reacts with human DEC-205 under conditions that promote dendritic cell quiescence, wherein the mouse DEC-205 protein comprises the amino acid sequence of SEQ ID NO: 10.

19. (Previously Presented) The method of claim 18, wherein the preselected antigen is selected from the group consisting of allergens, autoantigens and antigens participating in allograft rejection.

20. (Previously Presented) The method of claim 19, wherein the preselected antigen is bound to the antibody to DEC-205 by means of a cross-linking agent.

21. (Previously Presented) The method of claim 18, wherein a light chain or a heavy chain of the antibody to DEC-205, and the preselected antigen, are present on a single polypeptide chain.

EVIDENCE APPENDIX

Appendix B is a copy of the Declaration by Dr. Michel Nussensweig, which was entered by the Examiner in conjunction with the Amendment and Response filed by Appellants on January 4, 2005.

Appendix C is a copy of Guo *et al.* (Hum Immunol. 2000 Aug; 61(8):729-38), which was referenced in the Declaration by Dr. Michel Nussensweig and cited in an Information Disclosure statement (dated December 27, 2005) that was considered and initialed by the Examiner on March 19, 2006.

RELATED PROCEEDINGS APPENDIX

Please note that while a Pre-Appeal Brief Request for Review and related Appeal have been filed in the parent application, U.S.S.N.: 09/586,704 (filed June 5, 2000), a Notice of Panel Decision from Pre-Appeal Brief Review has not yet issued.

STIC Biotechnology Systems Branch

CRF Problem Report

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) experienced a problem when processing the following computer readable form (CRF):

Application Serial Number: 09/925,284
Filing Date: 08/09/04
Date Processed by STIC: 12/30/2006

STIC Contact: **Mark Spencer: Telephone: 571-272-2510; Fax: 571-273-0221**

Nature of Problem:

The CRF (was):

____ (circle one) Damaged or Unreadable (for Unreadable, see attached)
__✓__ Blank (no files on CRF) (see attached)
____ Empty file (filename present, but no bytes in file) (see attached)
____ Virus-infected. Virus name: _____ The STIC will not process the CRF.
____ Not saved in ASCII text
____ Sequence Listing was embedded in the file. According to Sequence Rules, submitted file should **only** be the Sequence Listing.
____ Did not contain a Sequence Listing. (see attached sample)
____ Other:

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PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM TO REDUCE ERRORS. SEE BELOW FOR ADDRESS:

http:/www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom. Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<**http://www.uspto.gov/ebc/efs/downloads/documents.htm**>, **EFS Submission User Manual** - ePAVE)
2. **U.S. Postal Service**: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. **Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05)**: U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Hawiger *et al.*	Examiner:	Ronald B. Schwadron
Serial No.:	09/925,284	Group Unit:	1644
Filed:	August 9, 2001		
For:	ENHANCED ANTIGEN DELIVERY AND MODULATION OF THE IMMUNE RESPONSE THEREFROM		

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage in an envelope addressed to MS APPEAL BRIEF-PATENTS, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on May 14, 2007.

Loretta Kavanagh
(Name of Person Depositing Mail)

Loretta Kavanagh 5/14/2007
(Signature of Person Depositing Mail)

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following remarks are responsive to a Notification of Non-Compliant Appeal Brief, dated March 14, 2007.

REMARKS

Applicants received a Notification of Non-Compliant Appeal Brief dated March 14, 2007, wherein the Examiner asserts that the Appeal Brief filed on November 27, 2006 is defective for the following reasons.

Support for the Claimed Methods

The Examiner asserts that the Appeal Brief does not disclose where the claimed methods find support in the specification as required by 37 C.F.R. § 41.37 (c)(1)(v)). The Examiner further states that "[w]hilst the claims use DEC-205, they are not drawn to DEC-205, but methods which use DEC-205."

In response, Appellants acknowledge that the claims on appeal are not drawn to DEC-205 *per se*, but are instead drawn to methods which employ DEC-205 vaccine conjugates. However, since DEC-205 vaccine conjugates are a critical component of the claimed methods, it is nearly impossible to isolate and separate support for the presently claimed methods from support for DEC-205 vaccine conjugates. Indeed, support for both DEC-205 vaccine conjugates and the presently claimed methods, which employ such conjugates, is intertwined in the specification.

For example, Appellants respectfully submit that the passages from the specification recited in the "Summary of the Claimed Subject Matter" set forth on pages 2-3 of the Appeal Brief) do indeed explicitly support the presently claimed methods, as well as the individual elements used in the methods (*i.e.*, DEC-205 vaccine conjugates). Thus, contrary to the Examiner's assertion, the Appeal Brief filed on November 27, 2006 complies with 37 C.F.R. § 41.37 (c)(1)(v)).

Evidence Appendix

The Examiner asserts that the Evidence Appendix does not disclose where the cited evidence was entered by the Examiner, as required by 37 C.F.R.§ 41.37 (c)(1)(v)).

In response, Appellants respectfully note that the Declaration by Dr. Michel Nussensweig (Appendix B) referred to in the Evidence Appendix was originally

submitted with the Amendment and Response filed by Appellants on January 4, 2005. Although the Examiner never formally indicated that the Declaration was entered, Appellants assume that the Declaration was, in fact, entered along with Appellant's Amendment and Response, since the Examiner specifically referenced the Declaration in the subsequent Office Action dated July 22, 2005 (see page 4, paragraph 1 of the Office Action). As such, Appellant's failure to indicate where the cited evidence was entered by the Examiner was due to the fact that the Examiner never formally acknowledged entry of the Declaration. This should not, however, preclude Appellants from citing the Declaration as evidence in the Appeal Brief, since the Declaration was indeed clearly entered. Notwithstanding, Appellants have amended the Evidence Appendix to state that the Declaration was entered with Appellant's Amendment and Response filed on January 4, 2005 under the assumption that this is correct.

Further, the Examiner notes that the Guo *et al.* reference (*Hum Immunol.* 2000 Aug; 61(8):729-38) was not filed on January 4, 2005, but was instead filed on December 27, 2005.

In response, Appellants respectfully note that this reference was cited *within* the Declaration by Dr. Michel Nussensweig (submitted with the Amendment and Response filed by Appellants on January 4, 2005) and thus, for the sake of completeness, Appellants provided a copy of this reference as evidence in the Appeal Brief. Notwithstanding, Appellants confirm the Examiner's statement that the reference itself was not filed on January 4, 2005, but was instead cited in an Information Disclosure statement filed by Appellants on December 27, 2005. Accordingly, the replacement Appeal Brief submitted herewith contains an amended Evidence Appendix (page 14), which specifies that Guo *et al.* (Appendix C) was cited in an Information Disclosure Statement dated December 27, 2005.

CRF Diskette Problem Report

The Examiner indicates that the Brief is non-responsive to paragraph 3 of the Office Action dated March 28, 2006. Specifically, Paragraph 3 indicates that the computer readable form (CRF) of the Sequence Listing that was submitted by Appellants

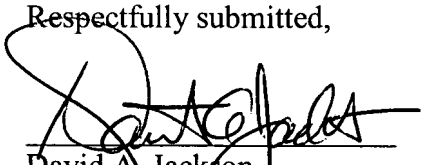
was blank. In response, Appellants submit herewith a replacement CRF of the Sequence Listing, as well as a copy of the CRF Problem Report, thereby rendering this issue moot.

CONCLUSION

Responsive to the foregoing issues, Appellants submit herewith a replacement Appeal Brief, which contains an amended Evidence Appendix, found on page 14 and request that this Appeal Brief replace the original as filed on November 27, 2006. Applicants assert that the replacement Appeal Brief corrects the deficiencies noted in the Notification of Non-Compliant Appeal Brief.

No fees are believed to be required for the present response, but if this is in error, the Commissioner is hereby authorized to charge any fees, or credit any overpayment, to Deposit Account No. 11-1153.

Respectfully submitted,



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Enclosures: Replacement Appeal Brief
Replacement CRF of Sequence Listing
Copy of CRF Problem Report, dated 12/30/2005